

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on May 23, 2011.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 15 days before the close of the written comment period.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference. Pursuant to the authority vested by Section 4005 of the Business and Professions Code, and to implement, interpret or make specific Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207 and 4400 of the Business and Professions Code, the Board of Pharmacy is considering changes to Section 1793.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board of Pharmacy proposes to amend Section 1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations and to update Authority and Reference citations.

Existing regulation at Section 1793.5 requires an applicant for a pharmacy technician registration to submit an application to the board. The application, Form 17A-5 (Rev. 9/94) is incorporated by reference; this proposed regulation repeals this application and incorporates by reference a new Pharmacy Technician Application, Form 17A-5 with a revision date of January 2011. As proposed, the pharmacy technician application incorporates educational and licensing requirements currently found in Division 2 of Chapter 9 of the Business and Professions Code.

Existing regulation in subdivision (a) of Section 1793.5 refers to a pharmacy technician "registration." This proposal would amend that subdivision to refer to a pharmacy technician "license." This amendment is necessary to make the terminology in this section consistent with the board's statutory authority to issue a pharmacy technician "license" as specified in Business and Professions Code section 4202.

Existing regulation in subdivision (a)(3) of section 1793.5 requires an applicant for a pharmacy technician license to provide a signed statement as to whether the applicant has ever been convicted of or pled no contest to a violation, as specified. This proposal would remove this requirement in regulation, because this statement has been incorporated into the pharmacy technician application (17A-5) which is incorporated by reference. Thus, the amendment is necessary to remove a statement which is duplicative of information contained in the pharmacy technician application.

This proposal would add a new subdivision (a)(4) to current Section 1793.5 which would require an applicant for a pharmacy technician license to submit to the board with his or her application a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB). Business and Professions Code section 4207 specifies that the board shall make a thorough investigation to determine whether an applicant is qualified for the license being sought. The board has determined that the requirement to submit a Self Query Report, as specified in the proposal, is necessary and pertinent to the board's investigation to determine if a pharmacy technician applicant has been the subject of discipline in another state prior to making a license decision to grant or deny a license.

Existing regulation in subdivision (c) of Section 1793.5 specifies time frames in which an applicant will be notified of any deficiency in his or her application, and in which the board will notify an applicant of a decision on his or her application. This proposal would specify that the time frame in which the board will notify an applicant of a decision applies to the time period after which any investigation conducted by the board is complete. This amendment is necessary because in some cases the board's investigation cannot be completed and a decision to grant or deny a license cannot be made within 60 days of an application being deemed complete.

Existing regulation in subdivision (d) of Section 1793.5 references the fee that a pharmacy technician must pay to renew a license issued by the board. This proposal would replace the existing regulation reference with a statutory reference. The board's fee schedule was revised in 2009, and a new fee schedule was effective on January 1, 2010 (see Chapter 270, Statutes of 2009 at section 4400 of the Business and Professions Code). The proposed amendment is necessary to remove an obsolete reference and to provide a current reference to the fee that a pharmacy technician must pay to renew a license issued by the board.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact: The board has made an initial determination that the proposed

regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not affect a business; rather, it affects applicants (individuals) who are seeking licensure from the Board of Pharmacy.

The board determined that up to 50 percent of pharmacy technician applications have one or more deficiencies, which delays the processing of license applications. By incorporating by reference a Pharmacy Technician Application (17A-5) that reflects existing laws and regulations, the board believes that deficiencies will be reduced and that applications will be processed more timely.

Section 4207 of the Business and Professions Code requires the board to make a thorough investigation of an applicant for licensure to determine whether the applicant is qualified for the license being sought. Subdivision (d) of this section provides that the information requested by the board for this purpose shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act.

This proposal includes a requirement that a pharmacy technician applicant shall submit with his or her application a Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB). The Self Query Report will allow the board to determine if the applicant has been disciplined in another state prior to making a licensing decision.

Existing regulation in subdivision (c) specifies timeframes in which the board will notify an applicant of any deficiency of an application, and of the board's decision to grant or deny a license. This proposal will specify that once an application is deemed complete, and upon completion of any investigation conducted, as specified, the board will then notify the applicant of a licensing decision.

Existing regulation at subdivision (d) of Section 1793.5 provides a regulatory reference related to the renewal fee a pharmacist technician must pay. This proposal would provide a more current reference, as the board's fee schedule was amended effective January 1, 2010. (See Chapter 270, Statutes of 2009, at section 4400 of the Business and Professions Code.)

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The agency is not aware of any cost impacts that a representative business would necessarily incur in reasonable compliance with the proposed action. The board estimates that a representative private person presently incurs approximately \$133 in reasonable compliance with the existing regulation. The board estimates that a representative private person may incur

additional costs of approximately \$28 in reasonable compliance with the proposed action. The board based this estimate on the following information and/or assumptions:

Estimate of Current Costs:

Application Fee	80.00	
Fingerprint Fees	51.00	
Paper, Envelope, Postage	2.00	
TOTAL		\$133.00

Estimate of Additional Costs:

NPDB Self-Query	8.00	
HIPDB Self-Query	8.00	
Paper, Envelope, Postage	2.00	
Notary Fee	10.00	
TOTAL		<u>\$28.00</u>

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not affect a business; rather, it affects applicants (individuals) who are seeking licensure from the Board of Pharmacy.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's Web site <http://www.pharmacy.ca.gov>.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Board of Pharmacy's Web site (www.pharmacy.ca.gov).

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Carolyn Klein
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	Carolyn.Klein@dca.ca.gov

The backup contact person is:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7910
Fax No.:	(916) 574-8618
E-Mail Address:	Anne.Sodergren@dca.ca.gov

Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.